[redacted] UNITED STATES [redacted] MENT OF COMMERCE
Pat nt and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/676,034	09/29/00	CAMDEN	J 6643R2

EXAMINER	
DELACROIX MUIRHEID, C	
ART UNIT	**PAPER NUMBER**
1614	5

HM22/0914

ROSE ANN DABEK
THE PROCTER & GAMBLE COMPANY
5299 SPRING GROVE AVENUE
CINCINNATI OH 45217

DATE MAILED: 09/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/676,034	CAMDEN et al.
Examiner	**Art Unit**
Cybille Delacroix-Muirheid	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-23 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3, 4

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Claims 1-23 are presented for prosecution on the merits.

Information Disclosure Statement

Applicant's Information Disclosure Statements received Nov. 20, 2000 and June 26, 2001 have been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

The Information Disclosure Statement received Oct. 30, 2000 has been considered in part, i.e. US patents only. The remaining references are not in parent application 08/857,811 and it is requested that the remaining references be submitted so that they may be considered and made of record.

Priority

Applicant's claim for priority to parent application 08/857,811 is noted. However, A claim can only have one effective filing date. Please see Studiengesellschaft Kahle m.b.H. v. Shell Oil Co., 42 USPQ2d 1674, 1677 (Fed. Cir. 1997). In the instant application the COOR1 group for substituent R has support in 08/857,811 which was filed May 16, 1997; however, the remaining chemical moieties for R and most of the moieties in R1 do not have support in the earlier filed parent application. Since the claim as whole can only have one effective filing date, the claims of the instant application will be treated as having an effective filing date of September 29, 2000. An intervening art applied in a rejection may be overcome by cancelling the relevant claim limitations or where appropriate, by submitting an affidavit or declaration under 37 CFR 1.131 to antedate the intervening art.

Claim Objections

1. Claims 2, 4, 5 are objected to because of the following informalities: in claims 2, 4, 5, the term "which" should be cancelled and replaced with the phrase --wherein the compound--. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to

the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Camden 6,077,862.

w/ d

Camden discloses the invention substantially as claimed. Specifically, Camden discloses a method of treating "all types of" cancers or viral infection in a warm-blooded mammal comprising administering effective amounts (15 to 1500 mg/kg body weight) of a compound represented by the general formula (see col. 5, lines 5-20), wherein R is COOR' and R' is haloalkyl, alkenyl and cycloalkyl. Preferred species are also discloses throughout the patent. The compounds may be in pharmaceutical form and may administered orally, topically, intravenously or parenterally. Camden additionally discloses that the compounds may be administered with chemotherapeutic agents and potentiators. Please see entire reference, especially col. 4, lines 45-65, col. 9, lines 1-45; col. 6, lines 14-19.

Camden does not specifically disclose that the R group is on a carbon of the benzene ring as claimed by Applicant. However, the compounds of Camden are structurally similar isomers useful as anti-cancer and anti-viral agents. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Camden to use the isomeric compounds claimed by Applicant because such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results.

5. Claims 1-11, 13 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Ram et al.(cited by Applicant in the IDS of Oct. 30, 2000) or Nasr et al.

Ram et al. disclose methods of studying the antineoplastic activity of benzimidazole compounds embraced by Applicant's claims. Please see abstract. Results show that the benzimidazole compounds inhibit the growth of leukemia cells. See abstract.

Nasr et al. Study the anti-cancer activity of benzimidazole compounds, for example Compound 8d in Table VIII. Results show that the compound exhibited good activity against leukemia cells. Please see the abstract; page 835, third full paragraph.

Ram et al. or Nasr et al. do not specifically disclose treating leukemia in a warm blooded animal; however, it would have been obvious to one of ordinary skill in the art to modify the methods of Ram et al. or Nasr et al. to include in vivo administration of the benzimidazole compounds to animals because in view of the desirable tumor growth inhibiting activities disclosed by Ram or Nasr et al., one of ordinary skill in the art would reasonably expect the compounds to effectively inhibit the growth of leukemia cells in animal patients.

Moreover, Ram or Nasr et al. do not disclose that the substituent group is on a carbon of the benzene ring as claimed by Applicant. However, the compounds of Ram and Nasr are structurally similar isomers useful as anti-cancer agents. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Ram or Nasr to use the isomeric compounds claimed by Applicant because such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results.

With respect to the claimed pharmaceutical forms of the compounds and modes of administration, these are all art-recognized, result-effective variables and it would have been obvious to one of ordinary skill in the art to modify them in the prior art.

Concerning the claimed dosage amounts, since the efficacy of a drug is dependent upon its dosage, it would have been obvious to one of ordinary skill in the art to further modify the teachings of Ram or Nasr such that the benzimidazole compounds are administered in amounts which are effective in treating leukemia in animals.

Finally, Ram or Nasr et al. do not teach combining the benzimidazole compounds with a chemotherapeutic agent and/or potentiators; however, it would have been obvious to one of ordinary skill in the art to combine known chemotherapeutic agents and potentiators with the anti-neoplastic compounds taught by Ram et al. because one of ordinary skill in the art would reasonably expect the additive effect of these compounds to more effectively treat the animal suffering from cancer, i.e. leukemia.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 23 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,077,862. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and USPN '862 claim a method for treating a viral infection in a warm-blooded animal, the method comprising administering effective amounts of the claimed benzimidazole compounds. The difference between the instant application and USPN '862 is that USPN '862 claims a more limited subgenus of compounds. Yet, the scope of the claims of the instant application and USPN '862 overlap because at least one of the substituents identified for R (which also corresponds to R in USPN '862) is identical to the substituents defined in R of USPN '862.

Moreover, the compounds of the instant application are structurally similar isomers of the compounds claimed in USPN '862 and are therefore obvious over one another.

8. Claims 1-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending application No. 09/676,031; claims 1-22 of copending Application No. 09/676,409; claims 1-22 of copending application No. 09/676,202; and claims 1-22 of application No. 676,029 . Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application and application No's. '029, '031, '202 and '409 claim methods for treating a cancer and a viral infection in a warm-blooded animal, the methods comprising administering

effective amounts of the claimed benzimidazole compounds. The difference between the instant application and the above copending applications is that the copending applications claim a more limited subgenus of compounds. Yet, the scope of the claims of the instant application and the copending applications overlap because at least one of the substituents identified for R in the instant application is identical to the substituents claimed in the copending applications, i.e. -NHCOR1 ('202), -CONR1R2 ('409), -COOR1 ('031) and -OCOR1 ('029).

Moreover, the compounds of the instant application are structurally similar isomers of the compounds claimed in the copending applications and are therefore obvious over one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-25, 30 and 36 of copending Application No. 08/857,811. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and copending application '811 claim a method for treating cancer in a warm-blooded animal, the method comprising administering effective amounts of the claimed benzimidazole compounds. The difference between the instant application and application '811 is that application '811 claims a more limited subgenus of compounds. Yet, the scope of the claims of the instant application and application '811 overlap because at least one of the substituents identified for R (which also corresponds to R in '811) is identical.

Moreover, the compounds of the instant application are structurally similar isomers of the compounds claimed in '811 and are therefore obvious over one another..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claim 23 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-20, 33-37 of copending Application No. 09/552,820. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and '820 claim a method for treating a viral infection in a warm-blooded animal, the method comprising administering effective amounts of the claimed benzimidazole compounds. The difference between the instant application and '820 is that '820 claims a more limited subgenus of compounds as well as a more specific method of treating HIV infection. Yet, the scope of the claims of the instant application and '820 overlap because at least one of the substituents identified for R (which also corresponds to R in '820) is identical, i.e. COOR'.

Moreover, the compounds of the instant application are structurally similar isomers of the compounds claimed in USPN '862 and are therefore obvious over one another..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1-23 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM

Sep. 9, 2001

Cybille Delacroix-Muirheid
Patent Examiner Group 1600